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PPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/695,369	10/23/2000	Wenfeng Xu	99-75	2902
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Robyn Adams ZymoGenetics, Inc. 1201 Eastlake Avenue East			EXAMINER	
			SAKELARIS	, SALLY A
Seattle, WA 9	98102		ART UNIT	PAPER NUMBER
			1634	Ø
			DATE MAILED: 07/01/2002	8

Please find below and/or attached an Office communication concerning this application or proceeding.

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Application No.	Applicant(s)
09/695,369	XU ET AL.
Examiner	Art Unit
Sally A Sakelaris	1634

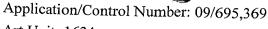
Office Action Summary -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply** A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). **Status** 1) Responsive to communication(s) filed on <u>23 October 2000</u>. 2a) This action is FINAL. 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. **Disposition of Claims** 4) Claim(s) <u>1-38</u> is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) \_\_\_\_\_ is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) 1-38 are subject to restriction and/or election requirement. **Application Papers** 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some \* c) ☐ None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

recommends)	
1) Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413) Paper No(s)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal Patent Application (PTO-15)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	6) Other:

a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(c)



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## RESTRICTION/ELECTION

- 1. Restriction to one of the following inventions is required under 35 U.S.C. §121:
- I. Claims 1-8, 17, and 27-34 are drawn to isolated polypeptides as classified in Class 530, subclass 350.
- II. Claims 9-16 and 35-38 are drawn to polynucleotides, vectors, host cells and methods for expression of polypeptides, classified in Class 435, subclasses 69.1, 252.3, and 320.1, Class 536, subclass 23.5, 24.31 and 24.33.
- III. Claims 18 and 19 are drawn to a method of detecting with a polynucleotide(see 19a).-u).) as classified in Class 435 subclass 6.
- IV. Claims 19 and 20-23 are drawn to a method of detecting a protein with an antibody as classified in Class 435 subclass 7.1.
- V. Claims 24-26 are drawn to a method of inhibiting and modulating by administering a polypeptide as classified in Class 514, subclass 7.1.
- 2. The inventions are distinct, each from the other because of the following reasons:
- a. Inventions I and II are patentably distinct in structure and physiochemical properties.

  Invention I is drawn to polypeptides whereas invention II is drawn to nucleic acids. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the compositions are utilized in different methodologies, such that nucleic acids may be utilized in hybridization

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assays, while the proteins may be utilized in ligand binding assays or to generate antibodies. The protein of invention I does not require the particular products of the nucleic acids of group II since the proteins of invention I can be isolated from natural sources or chemically synthesized.

- b. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of invention I can be used in a materially different process such as for generating antibodies.
- c. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the polypeptides of invention I are not required to practice the methods of inventions IV involving antibodies.
- d. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of invention I can be used in a materially different process such as in therapeutic methods.

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- e. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention II can be used in a materially different process such as for synthesizing proteins or for therapeutic purposes.
- f. Inventions II and IV and II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the nucleic acids of invention II are not required to practice the methods of inventions IV and V involving antibodies and polypeptides respectively.
- g. Inventions III and IV, III and V, and IV and V are drawn to patentably distinct methods which involve different method steps, include different reagents and have different objectives. Invention III involves a method of detecting using a polynuceotide. The invention of Group IV is drawn to a method of detecting using an antibody. Group V is drawn to a method of inhibiting and modulating by administering a polypeptide. The methods all have different method steps, objectives and reagents. Therefore the methods are distinct over one another.

## Restriction Requirement Applicable to All Groups:

3. Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differs in structure and in function and in biological activity. A restriction is applied to each Group. For an elected

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Group drawn to a nucleotide sequence, the Applicants must elect a single nucleic acid sequence from SEQ ID NOS: 1, 31, 32, 33, and 36, a single nucleic acid encoding a polypeptide from SEQ ID NOS: 2, 27, 29, 32-35 and 38. If applicant elects an invention drawn to polypeptides, Applicant must elect a single polypeptide from SEQ ID NOS: 2, 27, 29, 35, and 38. For an invention drawn to methods that use an antibody, Applicant must elect a single antibody to the polypeptides from SEQ ID NOS: 2, 27, 29, 35, and 38(See MPEP 803.04).

The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Similarly, proteins comprising unique amino acid sequences are structurally and functionally distinct. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter and because these inventions require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

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5. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Friday from 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantai Dessau whose telephone number is (703)605-1237.

Sally Sakelaris

6/26/02

CARLA J. MYERS
PRIMARY EXAMINER